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IN THE

Supreme Court Of The United States

LABORATORY CORPORATION OF AMERICA HOLDINGS, DBA LABCORP, PETITIONER

v.

METABOLITE LABORATORIES, INC., ET AL., RESPONDENTS

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF AMICUS CURIAE PEOPLE'S MEDICAL SOCIETY IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to "correlat[e]" test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result.

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STATEMENT OF INTEREST OF AMICUS CURIAE PEOPLE'S MEDICAL SOCIETY[1]

Amicus Curiae People's Medical Society, an Internal Revenue Code Section 501(c)(3) non-profit organization, is the largest patients' advocacy group in the United States and is a recognized authority on health care issues. Its mission is to enhance the availability of health care information to consumers and to encourage the health care system to be more responsive to consumers. The People's Medical Society is regularly consulted by government agencies, health care institutions, and companies designing health care products and pharmaceuticals for insights into the patients' perspective. The Society has served in an advisory capacity to the Health Care Financing Administration of the Federal Department of Health and Human Services on Medicare issues, and its current president, Charles Inlander, is a member of the Medical Error and Drug Safety Committee of the National Academy of Sciences, Institute of Medicine. As President of the People's Medical Society, Mr. Inlander has also served as a health commentator for National Public Radio in over 250 broadcast segments.

Since its inception in 1983, the People's Medical Society has released over 100 books, as well as hundreds of articles, fact sheets, and newsletters pertaining to the diagnosis and treatment of medical conditions. Over 7,000,000 copies of its books have been sold; the value of the medical information in these books is attested to by the honors these books have been accorded.[2] These publications further the

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[1] Pursuant to S. Ct. R. 37.6, People's Medical Society states that neither petitioner's nor respondents' has authored any portion of this brief. No financial contribution was made for preparation of this brief by anyone other than *Amicus* and its counsel. By letters filed with the Clerk of the Court, the parties have consented to the filing of this brief.

[2] For example, Charles Inlander et al., *Medicine on Trial* (Prentice Hall, 1988) was honored as Book of the Year by the American Nursing Association's *American Nursing Journal*. Charles Inlander, *The Men's*

organization's pledge "to put previously unavailable information into the hands of ordinary people so that they can make informed decisions about their own health care" and to "publish information designed to make every American a smart health care consumer."[3]

The activities of the People's Medical Society are designed to benefit patients by enhancing medical care, medical information, and medical research. If claim 13 of U.S. Patent No. 4,940,658 (the '658 patent) is upheld, each of these important activities will suffer. Moreover, if claim 13 is upheld, the charitable purpose of the People's Medical Society itself will be thwarted. The People's Medical Society could be construed to have done precisely what the Federal Circuit held actionable in this case. In its book, *Vitamins & Minerals: Questions You Have... Answers You Need* (1993), the People's Medical Society disclosed that homocysteine levels were related to vitamin deficiency.[4]

The unique voice of the People's Medical Society is particularly relevant in a patent case. In the United States, unlike Europe, there is no general procedure for third parties representing consumers to voice concerns at the time the U.S. Patent and Trademark Office is considering issuing a patent. Generally, the only entities that can challenge patents in litigation are entities that are themselves infringing the

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Health and Wellness Encyclopedia (MacMillan Publishing Company, 1998) was honored as reference book of the year by the New York Public Library, and the same honor was given in a previous year to Charles Inlander et al., *The People's Medical Society Health Desk Reference* (Hyperion Books, 1996).

[3] People's Medical Society: About the Society, *available at* <http:peoplesmed.org/abutmenu.html>.

[4] Q: How can I be checked for a B_{12} deficiency?

A: Blood tests are used. Usually a serum B_{12} test is done first. If that's low, physicians test to check for two other blood components associated with B_{12} deficiency: homocysteine and methylmalonic acid. . . .

Ellen Moyer, *Vitamins & Minerals : Questions You Have.. Answers You Need* 104 (People's Medical Society, 1993).

patent. In many instances, both sides in patent lawsuits have incentives to argue in favor of patentability of broad types of inventions and discoveries, even when challenging a particular patent, because each side in the dispute has its own patent portfolio it wants to protect or can readily pass royalty charges on to the consumer.[5] In contrast, the People's Medical Society does not hold any patents and thus can raise fundamental legal and policy concerns.

The lack of a mechanism for a consumer voice in the process for granting a patent is particularly troublesome, given the fact that much medical research in the United States is funded by the public. Over $27,887,512,000 in taxpayer funds were given to the National Institutes of Health (NIH) for medical research in 2004.[6] In fact, according to the '658 patent, the inventors relied on government funding for their work that led to the '658 patent. In addition, inventors' medical articles note their use of federal funding. *See, e.g.*, S.P. Stabler et al., *Elevation of Total Homocysteine in the Serum of Patients with Cobalamin or Folate Deficiency Detected by Capillary Gas Chromatography – Mass Spectrometry*, 81 J. Clin. Invest. 2, 466, 473 (February 1988).

The Court's decision in this case will have a substantial impact on patients, including those whose interests the People's Medical Society champions. It will also have an impact on the services the non-profit People's Medical Society performs.

SUMMARY OF ARGUMENT

The U.S. Constitution, Article I, Section 8, Clause 8, gives Congress the power "to promote the progress of

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[5] Lori B. Andrews, *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 3 Nature Reviews Genetics 805-806 (October 2002).

[6] National Institutes of Health, About NIH, *available at* <http://www.nih.gov/about/>, last updated on December 19, 2005.

Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." However, claim 13 of U.S. Patent No. 4,940,658 patent is not a "discovery" as that word is used in the Constitution, nor is it patentable subject matter under 35 U.S.C. § 101. Rather, it is an unpatentable law of nature.

Unlike situations in which a law of nature is merely part of a larger process, where the structure or process, when considered as a whole, is performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing), claim 13 of the '658 patent is nothing more than the naked patenting of a "law of nature." The Court's unbroken line of precedents preclude a finding of validity under 35 U.S.C. § 101 where a law of nature regarding a vitamin deficiency is sought to be patented in assays of any kind, whether inventive or not, when coupled with "correlating" -- *i.e.*, thinking about -- certain elevated results and vitamin deficiency. *See, e.g., Diamond v. Diehr*, 450 U.S. 175 (1981); *Parker v. Flook*, 437 U.S. 584 (1978); and *Gottschalk v. Benson*, 409 U.S. 63 (1972).

Upholding a patent centered on such "correlating" would also obliterate the protection for First Amendment activities provided by the Court's bar on the patentability of abstract ideas. The Federal Circuit's holding that physicians are culpable of direct infringement of claim 13 every time they think about or diagnose the relationship between homocysteine levels and a vitamin deficiency would have a chilling effect on protected speech and thought. Reaffirmation of this Court's precedents on the patentability of processes utilizing "laws of nature" is necessary to correct the constitutional imbalance the Federal Circuit's opinion would strike between Article I, Section 8, Clause 8 and the First Amendment of the U.S. Constitution.

Finally, upholding claim 13 of the '658 patent would have untenable policy implications. Enforcement of claim 13

will have a negative impact on medical care, the dissemination of medical information, and medical innovation. Upholding claim 13 of the '658 patent would also deter people from participating in medical research. Consequently, it is appropriate to overturn the decision of the Federal Circuit and hold invalid claim 13 of the '658 patent.

ARGUMENT

I. Background

The starting point for any analysis of patentability is the question, "What did the patent applicant invent?" *See, e.g.*, United States Patent and Trademark Office, Official Gazette Notices, November 22, 2005, Section II. With respect to claim 13 of U.S. Patent No. 4,940,658 (the '658 patent), what did the patent applicant invent? Metabolite Laboratories, Inc. and Competitive Technologies, Inc. (collectively "respondents") have not asserted that the patentee invented all methods of assaying homocysteine; in fact, clearly it did not since Abbott Laboratories invented another method, and indeed, alternate means of measuring homocysteine were available prior to the patent application and were disclosed in the patent application. Rather, what the patentee claims to have discovered is a relationship (correlation) between the levels of homocysteine and a deficiency of cobalamin or folate (vitamin deficiency). Under centuries of case law and patent policy, this relationship is an unpatentable law of nature.

The inventors in this case are physicians and scientists from non-profit institutions – Columbia-Presbyterian Medical Center, Columbia University, and the University of Colorado Health and Science Center. By analyzing blood from patients and blood donors, they observed that patients with a high level of homocysteine in their blood often had a vitamin deficiency. The inventors created a test for

measuring homocysteine levels, which is the subject of claims one through twelve of the '658 patent. Petitioner Laboratory Corporation of America Holdings (LabCorp) does not dispute that these claims are valid. It continues to pay royalties when it uses that test.

However, the inventors went further and included claim 13:

> A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:
>
> Assaying a body fluid for an elevated level of total homocysteine; and
>
> Correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

As this Court noted in its request for comment from the Solicitor General, claim 13 covers anyone who "measure[s] the level of the relevant amino acids using any device, whether the device is, or is not, patented; second, notice[s] whether the amino acid level is elevated and, if so, conclude[s] that a vitamin deficiency exists." *Laboratory Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 73 U.S.L.W. 3512, 3512 (U.S. Feb. 28, 2005). The Federal Circuit held that LabCorp induced infringement of claim 13 of the '658 patent based solely on the publication to physicians of a law of nature – the relationship between levels of homocysteine and vitamin deficiency. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1365 (2004). Astonishingly, the Federal Circuit also held that physicians infringed claim 13 merely by thinking about the relationship between homocysteine and vitamin deficiency. *Id.* at 1363-1365.

II. Claim 13 of the '658 Patent Is Not Patentable Subject Matter and Should be Held Invalid.

A. Claim 13 of the '658 Patent Is Not a "Discovery" Within the Meaning of Article I, Section 8, Clause 8 of the U.S. Constitution.

The U.S. Constitution, Article I, Section 8, Clause 8, grants Congress the power "to promote the progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

Throughout the '658 patent, the patentee describes its homocysteine assay (the patentability of which is not in dispute) as an "invention" and the relationship between homocysteine levels and vitamin deficiency as a "discovery."[7] However, this discovery does not rise to the level of a patentable discovery as contemplated by Article 1, Section 8, Clause 8 of the Constitution.

The term "Discoveries," as utilized in Article I, Section 8, Clause 8, is synonymous with "inventions." Writing in 1889, a patent law scholar noted that someone "may invent a machine, and may discover an island or law of nature. For doing the first of these things, the patent laws may reward him, because he is an inventor in doing it; but those laws cannot reward him for doing either of the others, because he is not an inventor in doing either." Albert A. Walker, *Text-Book of the Patent Laws of the United States of America* 2-3 (L. K. Strouse & Co., 2d ed. 1889).

> An "invention," in the parlance of the Constitution and early patent laws, is a new creation consciously sought and successfully

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[7] For example, in the "Summary of the Invention" section of the '658 patent, the relationship between homocysteine and vitamin deficiency is said to have been "discovered." U.S. Patent No. 4,940,658 col. 4, l. 17.

> reduced to practice by the inventor. A "discovery," as used in the same parlance, was intended to denote a fortuitous creation of the inventor and not merely something found by him or her. Thus, an "invention" and a "discovery" share the requirement that the inventor create something original; the difference between the two is that an "invention" is consciously sought, while a "discovery" is created unexpectedly. A discovery in that era, as used in the intellectual property law, denoted something originating from the human intellect and not merely learned by that intellect.

Linda J. Demaine and Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 Stan. L. Rev. 303, 370 (2002) (citation omitted).

The dichotomy between discoveries and inventions is similarly recognized under the patent laws of other countries. The European Patent Convention (EPC) requires an "inventive step," excluding mere "discoveries" from patentable subject matter. *See* European Patent Convention, Article 52(2) (1998). The EPC states that "discoveries, scientific theories and mathematical methods" are not regarded as patentable subject material. *Id.* The similarity between Europe and the United States on this point is in keeping with the thrust toward international intellectual property harmonization.[8]

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[8] "The Uruguay round of WTO negotiations introduced TRIPS into GATT and bravely attempted to harmonize global patent systems with uniform standards of protection. . . . Both the U.S. and the U.K. have made changes to their laws in response to these provisions. . . ." Thomas K. McBride, Jr., *Patent Practice in London – Local Internationalism: How Patent Law Magnifies the Relationship of the United Kingdom with*

Claim 13 of the '658 patent does not claim a discovery as contemplated by the U.S. Constitution, Article I, Section 8, Clause 8; therefore, claim 13 should be held invalid. The relationship between homocysteine levels and vitamin deficiency is a law of nature that exists independent of human intervention, invention, or manipulation. This relationship existed in mammals long before it was uncovered, so this correlation is not a new or an inventive innovation, but only the description of existing natural phenomenon, a law of nature. While "anything under the sun that is made by man" might be patentable, *Diamond v. Diehr*, 450 U.S. 175, 182 (1980) (citation omitted), the relationship of homocysteine to vitamin deficiency was not made by man.

Moreover, recognition of claim 13 of the '658 patent would also be contrary to the policies underlying Article I. The underlying goal of Article I, Section 8, Clause 8 was to "promote the progress of Science and the useful Arts," a goal that is not met in the case of a patent that restricts others from using a law of nature in their inventions.

B. Claim 13 of the '658 Patent Operates as an Unpatentable "Law of Nature" Under 35 U.S.C. § 101.

35 U.S.C. § 101 limits the categories of inventions that are patentable, stating "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." This Court has consistently held that laws of nature are not patentable. "This Court has undoubtedly recognized limits to § 101 and every discovery is not embraced within the statutory terms.

Europe, the United States and the Rest of the World, 2 Loy. U. Chi. Int'l L. Rev. 31, 47 (2004-2005).

Excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas." *Diehr*, 450 U.S. at 185. *See also Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 116 (1853); *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852).

This Court has pointed out that a scientific principle "reveals a relationship that has always existed." *Flook*, 437 U.S. at 593.[9] Consequently, "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Benson*, 409 U.S. at 71-72. In *Funk Bros.*, 333 U.S. at 130-131, the Court recognized that unpatentable laws of nature include biological phenomenon affecting naturally-occurring living organisms and held invalid a patent on a mixed culture of bacteria for use in the inoculation of seeds. While noting that the discovery was "ingenious," the Court held, "He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes." *Id.* at 130.

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[9] This logic is also underscored by the inherency doctrine in patent law. For example, in a 2002 case, the Federal Circuit held that a patent cannot be granted to an applicant who has discovered a natural attribute of a living entity. *In re Cruciferous Sprout Litigation*, 301 F.3d 1343 (Fed. Cir. 2002). In that case the Federal Circuit stated, "[T]he glucosinolate content and Phase 2 enzyme-inducing potential of sprouts necessarily have existed as long as sprouts themselves, which is certainly more than one year before the date of application . . . ." *In re Cruciferous Sprout Litigation*, 301 F.3d at 1350. Similarly, in the case at bar, the inventors did not create the relationship between homocysteine and vitamin deficiency. That relationship, like the enzyme-inducing potential of certain sprouts or the strength of pure tungsten (*see General Electric Co. v. DeForest Radio Co.*, 28 F.2d 641, 643 (3d Cir. 1928), *cert. denied* 278 U.S. 656 (1929)), previously existed in nature.

There are good policy reasons for not granting a patent applicant a patent on a law of nature. The Court in *Morse*, 56 U.S. (15 How.) at 113, expressed its concern that granting Samuel Morse broad rights to a law of nature for a generic purpose (the use of electromagnetic waves to write at a distance) beyond its particular application in Morse's concrete novel invention (the telegraph) would overcompensate the inventor by giving him rights to subsequent inventions that he himself did not create that used the law of nature governing electromagnetic waves. The Court was also concerned that such a large grant of rights would deter other inventors to the public's detriment. *Id* at 120-121.

The Court denied Morse's broad patent claim, stating:

> If this claim can be maintained, it matters not by what process or machinery the result is accomplished. For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification. His invention may be less complicated -- less liable to get out of order -- less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.

Id. at 113.

The Court's concern in *Morse* has come to pass in this case. Abbott Laboratories invented an alternative test for homocysteine levels that can be performed more efficiently, but use of it to assess the likelihood of vitamin deficiency is an infringement of the overly-broad patent claim 13 under

the logic of the Federal Circuit's decision. This holding gives patent rights not only to the test that the '658 patent inventors themselves patented, but to any test invented by anyone else that makes use of the law of nature about the relationship between elevated homocysteine levels and vitamin deficiency, even if that other test is more reliable, less expensive, simpler in use or operation, or performed by a new machine.[10]

C. Claim 13 of the '658 Patent Is Distinguishable From an Allowable Patent Claim Which Merely Incorporates a Law of Nature in a Larger, Patentable Process.

Despite the patentee's attempt to couch the claim as a two-step process, claim 13 is a naked patent claim on a law of nature and not a process within the meaning of 35 U.S.C. § 101. A process, as described by this Court in *Cochrane v. Deener*, 94 U.S. 780 (1877), and reaffirmed in *Diehr*, is a "mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing." *Diehr*, 450 U.S. at 183 (quoting *Cochrane*, 94 U.S. at 788). The Court in *Diehr* stated further, "transformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines." *Id.* at 184 (quoting *Benson*, 409 U.S. at 70).

It is undisputed that there is no "particular machine" to be utilized in claim 13. Nor can it be seriously maintained that there is a "transformation and reduction of an article to a

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[10] While Metabolite might argue that an alternative homocysteine test could be used without infringing claim 13 if the physician using the test does not then think about the relationship of the test results of vitamin deficiency, Metabolite's own witness, one of the inventors of the '658 patent, said physicians would necessarily think about that relationship or risk a malpractice lawsuit. *Metabolite Labs., Inc.*, 370 F.3d at 1364.

different state or thing" where any test, transforming or not, can provide the data that is called for by the first step.

Even if it could be shown that transforming is a necessary feature of all "assays," even those yet to be invented, it is clear that any such transformation is not the essence of the purported process in claim 13 as it was in *Diehr*. There the patentee transformed raw rubber into a final product usable by consumers. Transformation was the point of the process. Here, the acquisition of data, *i.e.*, the number representing the patient's homocysteine level, is the sole purpose of the first step. The mere gathering of data to apply a mathematical formula should not make the formula patentable, in the same way that inconsequential postsolution activities cannot convert an unpatentable principle into a patentable process. *Flook*, 437 U.S. at 590. Since the second step of claim 13 is merely a mental step, a conclusion based upon the scientific principle that elevated homocysteine levels mean vitamin deficiency in a certain percentage of the cases,[11] there is no process here. Data is gathered, and in a physician's mind a scientific principle is applied and a conclusion is drawn. That is all.

In addition, the file wrapper history in this case should estop Metabolite from claiming that claim 13 covers a two-step process. The history of this case shows an attempt to claim the use of a law of nature in a sweeping range of technologies as was prohibited in the *Morse* case. The patentee originally resisted adding a discrete separate step for claim 13 that would reveal enablement under 35 U.S.C. § 112, with the stunning party admission as follows:

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[11] According to a study of 7,747 patients in the '658 patent, the percentage of patients with vitamin deficiency accurately predicted by the test of homocysteine is 89%. Eleven percent of people with the vitamin deficiency are missed by the test. Moreover, 12% of healthy people on whom the homocysteine test and correlation are used will erroneously be told they have a vitamin deficiency. Because the test is not perfect, it is important not to deter subsequent innovation.

> "[A]s applicants are the first to detect cobalamin or folate deficiency by assaying body fluids for total homocysteine, it is believed that they are entitled to a claim of equivalent scope, *not limited to any particular steps or methods*."

Metabolite, 370 F.3d at 1362 (emphasis added).

Since step 1 of claim 13 specifies *any* kind of assaying for an elevated level of total homocysteine, and thus does not involve an inventive aspect, the Federal Circuit focused on step 2, "[t]he correlating step [which] is a simple conclusion that a cobalamin/folate deficiency exists *vel non* based on the assaying step. The patentee did not conceal or fail to disclose this correlation, but instead featured it as the centerpiece of the invention." *Id.* at 1367. Moreover, "the record shows repeatedly that the correlating step is well within the knowledge of one of skill in this art." *Id.* In short, there is no valid process patent when the applicant admits there is no process to begin with.

Patent law does not allow for exclusive control over a law of physiology, even if such a natural phenomenon is observed in a blood draw. Adding a "correlating" step to a process that is devoid of any other inventive step or aspect does not change that result. Moreover, thinking about a physiological principle is not a "process" or "method" or "art" under patent law. Rather, it is core First Amendment activity, unpatentable ideation.

However, assuming *arguendo* that the Court finds that claim 13 constitutes a "process," that process is more analogous to the processes found not to be patentable in *Benson* and *Flook* than to the *Diehr* process.

Benson and *Flook* hold that the process itself must be new and useful because the law of nature (or, in those cases, the mathematical algorithm) "whether known or unknown at the time of the claimed invention, [is]... one of the 'basic tools of scientific and technological work,' see *Gottschalk v.*

Benson, 409 U.S. at 67, and is treated as though it were a familiar part of the prior art." *Flook*, 437 U.S. at 591-92.

Under the standards of *Benson* and *Flook*, neither of the steps of claim 13 present an inventive aspect. Step one, the assay, fails because there is not a specific new and useful process involved. Rather, the patentee claims all assays for homocysteine, no matter what kind and no matter who actually invented the assay, without any means of enablement for the assays claimed. The second step, the application of the correlation, fails because it is merely the naked application of a law of nature, which is a basic tool of scientific work.

This contrasts greatly with the patentable process using a mathematical formula in *Diehr*. That was a specific process involving multiple steps,[12] involving a particular machine,

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[12] There were three claims at issue in *Diehr*, 450 U.S. at 179. The first claimed:

> 1. A method of operating a rubber molding press for precision molded compounds with the aid of a digital computer, comprising:
>
> 'providing said computer with a data base for said press including at least,
>
> 'natural logarithm conversion data (ln),
>
> 'the activation energy constant (C) unique to each batch of said compound being molded, and
>
> 'a constant (x) dependent upon the geometry of the particular mold of the press,
>
> 'initiating an interval timer in said computer upon the closure of the press for monitoring the elapsed time of said closure,
>
> 'constantly determining the temperature (Z) of the mold at a location closely adjacent to the mold cavity in the press during molding,
>
> 'constantly providing the computer with the temperature (Z),
>
> 'repetitively calculating in the computer, at frequent intervals during each cure, the Arrhenius equation for reaction time during the cure, which is
>
> 'ln v <v1>equ CZ+x
>
> 'where v is the total required cure time,

used for a specific application. In *Diehr*, this Court distinguished between process claims containing scientific principles "where the structure or process, when considered as a whole, is performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing)", 450 U.S. at 192, and those which are "seeking patent protection for [a] formula in the abstract," aided by a competent draftsman. *Id.* at 191.

Claim 13 of the '658 patent does not seek patent protection for the patentee's assay for homocysteine levels. That protection is claimed by other claims in the patent and is not here in dispute. What then does claim 13 add to the other claims? The answer is obviously the protection of the discovery of the relationship between elevated homocysteine levels and vitamin deficiency. Is this discovery the type that the patent laws were designed to protect? No, since it is most clearly a law of nature. By adding a step of using any means of gathering data, whether patentable or not, to apply in a law of nature, does the process as a whole become something the patent laws were designed to protect or is it still just the law of nature, claimed through a clear subterfuge of a competent draftsman? All laws of nature require the input of data to apply the law. Hence, any such law could be drafted as a two or three step process, e.g. obtain a reading for x, apply the law that x = y, conclude y.

This purported process contains none of the touchstones this Court has used to winnow properly protectable process claims from the overreaching claims of those who discovered natural laws and sought to monopolize them. It does, however, contain a cleverly drafted breakdown of a one-step scientific principle into a purported two-step process. It is

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'repetitively comparing in the computer at said frequent intervals during the cure each said calculation of the total required cure time calculated with the Arrhenius equation and said elapsed time, and

'opening the press automatically when a said comparison indicates equivalence.'

precisely the type of claim this Court sought to prevent in *Benson* and *Flook*.

Moreover, the Federal Circuit ruled that claim 13 of the '658 patent is infringed simply by a physician thinking in his or her head after receiving the results of a body fluid assay that the level of homocysteine is or is not correlated to a vitamin deficiency of cobalamin or folate. *Metabolite Labs., Inc.*, 370 F.3d at 1363-1365. This thought process proceeds entirely inside the physician's head and is essentially, a physician applying a biological fact to his patient. The physician's mere thoughts were found to be infringement. Yet, mental processes have specifically been ruled by the Supreme Court to be unpatentable subject matter in *Benson*, 409 U.S. at 67, and *Flook*, 437 U.S. at 589, so this step alone cannot serve as a basis to uphold claim 13.

The potential harms to the public in upholding an inappropriate claim on a law of nature involving a medical fact are particularly grave. Erroneously granted patents on computer programs or a business method are unlikely to kill someone. Discouraging physicians from learning about or thinking about a medical fact could.

III. Patent Protection for Claim 13 of the '658 Patent Chills the Exercise of First Amendment Rights.

Both the patent law and the First Amendment have a common goal: to encourage the expansion of knowledge through disclosure. The patent law encourages disclosure of inventions to seed future innovation in the technological sphere. *See, e.g. Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989) ("the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure"). The First Amendment encourages a marketplace of ideas. U.S. Const., amend. I.

When the U.S. Patent and Trademark Office grants a patent that can be used to prohibit a physician from thinking

about a medical fact, and prohibits anyone other than the patent holder from publishing that medical fact, First Amendment values are implicated.

A. Claim 13 of the '658 Patent Chills the Exercise of Freedom of Thought.

Certain rights are inherent in the expressly enumerated rights of speech and the press and must be preserved to effectuate the principles of the First Amendment. For example, this Court has consistently recognized the importance of freedom of thought, the ability to form or hold a belief prior to its expression, as a right inherent in the First Amendment. *See Wooley v. Maynard*, 430 U.S. 705, 714-715 (1977); *Palko v. Connecticut*, 302 U.S 319, 326-327 (1937). This is in keeping with precedents recognizing that the First Amendment protects other activities which are precursors necessary to the formulation of expression, communication and publication. *Richmond Newspapers v. Virginia*, 448 U.S. 555, 556 (1980); *Globe Newspaper Co. v. Superior Court*, 457 U.S. 596, 604 (1982).

Freedom of thought is a fundamental right necessary for the existence of freedom of speech and of the press. "The guarantee of free expression...is inextricably linked to the protection and preservation of open and unfettered mental activity." Laurence Tribe, *American Constitutional Law* § 15-7, at 1322 (2d ed. 1988). As Justice Cardozo stated, "freedom of thought...is the matrix, the indispensable condition, of nearly every other form of freedom. With rare aberrations a pervasive recognition of that truth can be traced in our history, political and legal." *Palko*, 302 U.S. at 326-327.

In this case, the Federal Circuit stated that "the parties hinge the direct infringement issue solely on whether the physicians perform the correlating step," *Metabolite Labs., Inc.*, 370 F.3d at 1364, even though that correlation was done entirely in the physicians' minds. Thus, the Federal Circuit

held that the physicians directly infringed Metabolite's claim 13 by thinking that a homocysteine level may signify a vitamin deficiency. Consequently, the granting and enforcement of claim 13 chills the exercise of freedom of thought.

The progress of scientific achievement is imperiled when a patent claim such as claim 13 asserts as private intellectual property basic scientific information. Because of the enforcement of claim 13, physicians in clinics and in research institutions will be prohibited from thinking about the correlation between elevated levels of homocysteine and vitamin deficiency unless they pay the toll of using Metabolite's test.

B. Claim 13 of the '658 Patent Chills the Exercise of Freedom of Speech.

The Federal Circuit held that LabCorp indirectly infringed claim 13 of the '658 patent by publishing basic scientific information. *Id.* at 1364-65. Such a holding chills the exercise of freedom of speech. This result denies physicians hoping to treat ill patients access to basic scientific information and restricts the ability of other scientists to undertake further research regarding the information and publish the results of that research.

The slim reason why over $4 million in damages were assessed against LabCorp was that they induced infringement by publishing an article about the homocysteine-vitamin deficiency relationship. But it is difficult to imagine how the publication of a previously-known and previously-published fact could be found to have induced infringement. Arguably, LabCorp did not induce infringement when it informed physicians about the relationship between homocysteine levels and vitamin deficiency because physicians already knew about that relationship. In fact, the association is so well-known that one of the inventors said it would violate the standard of care for physicians not to apply that known

association.[13] The '658 patent itself revealed the association. At least 22 articles in the medical literature written by the inventors themselves before the publication of the LabCorp article disclosed the correlation.[14] In addition, other physicians and scientists published articles in the medical literature revealing that correlation.[15]

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[13] The inventor said "that it would be malpractice for a physician to receive a total homocysteine assay without determining cobalamin/folate deficiency." *Metabolite*, 370 F.3d at 1364.

[14] A search of www.pubmed.gov, which is a search engine provided by the National Center for Biomedical Information, the National Library of Medicine, and the National Institute of Health created to disseminate biomedical information, located 22 articles that disclosed the homocysteine and vitamin deficiency correlation prior to the date Laboratory Corporation of America distributed its publication of the correlation to physicians. *See e.g.*, A.M. Kuzminski et al., *Effective Treatment of Cobalamin Deficiency with Oral Cobalamin*, 92 Blood 4, 1191-98 (1998); A.E. Sumner et al., *Elevated Methylmalonic Acid and Total Homocysteine Levels Show High Prevalence of Vitamin B_{12} Deficiency After Gastric Surgery*, 124 Ann. Intern. Med. 5, 469-76 (1996); J. Lindenbaum et al., *Prevalence of Cobalamin Deficiency in the Framingham Elderly Population*, 60 Am. J. Clin. Nutr. 1, 2-11 (1994); D.G. Savage et al., *Sensitivity of Serum Methylmalonic Acid and Total Homocysteine Determinations for Diagnosing Cobalamin and Folate Deficiencies*, 96 Am. J. Med. 3, 239-46 (1994); S.P. Stabler et al., *Elevation of Total Homocysteine in the Serum of Patients with Cobalamin or Folate Deficiency Detected by Capillary Gas Chromography-Mass Spectrometry*, 81 J. Clin. Invest. 2, 466-74 (1988).

[15] *See e.g.*, H. Ono et al., *Plasma Total Homocysteine Concentrations in Epileptic Patients Taking Anticonvulsants*, 46 Metabolism 8, 959-62 (1997); S.E. Miner et al., *Clinical Chemistry and Molecular Biology of Homocysteine Metabolism: An Update*, 30 Clin. Biochem. 3, 189-201 (1997); E. Joosten et al., *Is Metabolic Evidence for Vitamin B-12 and Folate Deficiency More Frequent in Elderly Patients with Alzheimer's Disease?*, 52 J. Gerontol A. Biol. Sci. Med. Sci. 2, M76-9 (1997); J. Metz et al., *The Significance of Subnormal Serum Vitamin B_{12} Concentration in Older People: A Case Control Study*, 44 J. Am. Geriatr. Soc. 11, 1355-61 (1996); Jensen M. Krogh et al., *Folate and Homocysteine Status and Haemolysis in Patients Treated with Sulphasalazine for Arthritis*, 56 Scan J. Clin. Lab. Invest. 5, 421-9 (1996); E. Joosten et al., *Cobalamin Absorption and Serum Homocysteine and Methylmalonic Acid in Elderly*

By prohibiting further publication of the homocysteine-vitamin deficiency relationship, enforcement of claim 13 runs afoul of this Court's First Amendment holdings that "the state may not, consistently with the spirit of the First Amendment, contract the spectrum of available knowledge." *Griswold v. Connecticut*, 381 U.S. 479, 482 (1965).

IV. Allowing Claim 13 of the '658 Patent to Stand as Valid Would Have Untenable Policy Implications.

A. Upholding Claim 13 of the '658 Patent Would Have a Negative Impact on Health Care in the U.S.

The enforcement of claim 13 of the '658 patent creates a patent infringement when a physician thinks about a law of nature, a medical fact. There is no fair use exception, unlike in copyright law. 17 U.S.C. § 107. There is only a very narrow research exception, so narrow as to be declared by commentators as "for all practical purposes a nullity." Janice M. Mueller, *The Evanescent Experimental Use Exemption from the United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 Baylor L. Rev. 917, 962 (2004). *See also* Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 Wis. L. Rev. 81, 87 (2004); *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002). This contrasts with the broad experimental use exceptions in other countries. Gen'l Secretariat of the Council of the Eur. Communities, Records of the Luxembourg Conference on the Community Patent 1973, art. 31(b), at 302; *see also* William R. Cornish, *Experimental Use of Patented Inventions in European Community States*, 29 Int'l Rev. Indus. Prop. & Copyright L. 735, 735-36 (1998),

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Subjects with Low Serum Cobalamin, 51 Eur. J. Haematol. 1, 25-30 (1993).

Scrutiny of claim 13 of the '658 patent is particularly important because it can affect people's health. Vitamin deficiency is a major-public health problem. It "can cause serious illnesses in humans, including vascular disease, cognitive dysfunction, birth defects and cancer. If detected early enough, however, vitamin supplements readily treat the deficiency." *Metabolite Labs., Inc*, 370 F.3d. at 1358.

If claim 13 of the '658 patent is declared valid, patients' medical care will suffer. Physicians (other than those who have ordered a test from the patent holder) will be deterred (on penalty of patent infringement) from recognizing in their patients the association between the level of homocysteine and vitamin deficiency. It will also impede health care if, every time a health care provider or medical laboratory technician is about to diagnose a patient, he or she has to stop, mid-thought, and undertake an extensive patent search.[16]

International conventions about intellectual property rights, to which the United States is a signatory, provide that patent rights should give way to health concerns in certain instances. For example, the Agreement on Trade Related Aspects of Intellectual Property Rights of the World Trade Organization, promulgated in 1995, highlights how public health can be given greater weight than the commercial concerns of patentees. Agreement on Trade-Related Aspects of Intellectual Property Rights, Dec. 15, 1993, 33 I.L.M. 81 (1994) (hereinafter TRIPS). Article 27 of TRIPS specifically

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[16] Since the medical fact might, as in the case under consideration, have been patented prior to 1996, physicians will have to do patent searches for all medical facts, even though ultimately some physicians might be protected by the limited safe harbor for physicians under 35 U.S.C. § 287(c). Even with respect to post-1996 patents, however, the protection of § 287 will not apply to other individuals who supply medical information, such as a Ph.D. in genetics who applies a medical correlation about a particular gene mutation and breast cancer, or a group that publishes medical information, such as the People's Medical Society.

allows governments to exclude from patentability diagnostic, therapeutic, or surgical methods. *Id.*

The enforcement of claim 13 of the '658 patent increases the cost of health care and impedes appropriate medical care by improperly interfering with physicians' and patients' ability to gain information about a medical fact and to think about that fact.

B. Upholding Claim 13 of the '658 Patent Would Have a Negative Impact on the Dissemination of Medically Relevant Information.

The enforcement of claim 13 of the '658 patent interferes with the free flow of information about a scientific fact of great relevance to the health of individuals. In this case, the offending publication provides just the sort of information that health care providers and consumers need – information about both the diagnosis and treatment of vitamin deficiency. *Metabolite*, 370 F.3d at 1365. If claim 13 is upheld, entities that wish to publish information about the relationship between homocysteine and a vitamin deficiency – a true medical fact – will be deterred from doing so by the cost of patent royalties or the possibility of millions of dollars in damages for induced infringement.

The absurdity of Metabolite's position in this case is illustrated by the following example: it would not induce infringement of claim 13 if the People's Medical Society published an article saying, "There are several tests for homocysteine levels. We recommend that you get the test from Abbott Laboratories." However, if People's Medical Society attempted to further its non-profit mission by providing information to consumers and added, "An elevated level on a homocysteine test can indicate whether you have vitamin deficiency," that statement would induce infringement of the patent. Clearly, claim 13 deters publication of medical information.

Upholding claim 13 of the '658 patent would also create an incentive for other companies to assert patent rights over other scientific facts, further increasing the cost of health care and diminishing the flow of medical information.

C. Upholding Claim 13 Would Have a Negative Impact on Innovation.

Patent law has one underlying policy aim -- to encourage innovation. The mechanism by which that is achieved is by granting the patent holder a monopoly on any use of the patented invention in exchange for a disclosure in the patent application of how exactly the invention can be made. This encourages innovation by stimulating people to invent in the first place, often by making a better, cheaper, more interesting, and more effective alternative to an existing invention. Thus, if a person patents a mousetrap made of wood, when the patent application later becomes public (a condition of the patent grant), other inventors can read about how the inventor made the mousetrap and can create novel variations using significantly different materials or processes. *See Graham v. John Deere Co.*, 383 U.S. 1, 8-9 (1966).

Here, claim 13 deters innovation by preventing researchers from thinking about or further exploring the relationship of homocysteine and vitamin deficiency. Even though another inventor could create a better homocysteine test, perhaps one with a 99% correlation rather than the 89% correlation of the Metabolite test, that inventor would not be able to make his better test available because users of the test would invariably think that the homocysteine levels measured by the test were related to vitamin deficiency.

By chilling the publication of information about the relationship between homocysteine levels and vitamin deficiency, claim 13 will operate to deter researchers from developing treatments for vitamin deficiency. In fact, if a potential funder of research into treatments for vitamin deficiency described the homocysteine-vitamin deficiency

relationship in a published solicitation for research proposals, it could be liable for inducing infringement.

D. Upholding Claim 13 Would Deter People From Participating in Medical Research.

Many patients served as research subjects and gave generously of themselves so that the inventors of the '658 patent could recognize an inherent biological phenomenon, the law of nature that high homocysteine levels correlate with vitamin deficiency. According to the '658 patent, at least 301 of these patients were subjected to full clinical evaluations including risky neurological evaluations, blood and bone marrow smears, and repeated serum tests for antibodies to intrinsic factor for a period of two years. In all, 7,987 patients were studied and tested to discover the patented relationship between homocysteine and vitamin deficiency. There is no evidence in the patent or in the publications by the inventors that the patients were informed that medical information from their bodies would be patented.[17]

Upholding claim 13 is likely to have a deterrent effect on people's willingness to participate in research. Why should someone altruistically give of their time and subject themselves to potential physical risks if this leads to a patent on a medical fact, increasing health care costs and deterring innovation? As a result of this case, patients who are potential research subjects are aware now that their altruistic

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[17] Case law and medical ethics underscore the importance of such disclosures. *See, e.g., Moore v. Regents of the University of California*, 51 Cal.3d 120, 793 P.2d 479 (1990). The AMA Code of Ethics Section 2.08 (3), provides "Human tissue and its products may not be used for commercial purposes without the informed consent of the patient who provided the original cellular material." American Medical Association, Council on Ethical and Judicial Affairs, *Code of Medical Ethics: Current Opinions with Annotations*, Section 2.08 Commercial Use of Human Tissue (Chicago: AMA, 2000).

participation in research, often at the cost of physical pain and risk, might lead to medical facts being patented which would increase the cost of their health care and interfere with its quality. This is exactly what happened to the 7,987 people who participated in this study, some of whom had painful bone marrow fluid extractions without knowing that the law of nature discovered in their bodies would be patented. It would be reasonable for people to lose interest in being research subjects if the laws of nature discovered in their bodies lead to patents that can be enforced to their detriment.

E. Adherence to the Law of Nature Doctrine Will Not Stifle Innovation.

The Court should not forsake its strict adherence to its laws of nature non-patentability doctrine which is of constitutional as well as statutory dimension. Both Article I, Section 8, Clause 8 and the First Amendment provide breathing room for the public domain of abstract ideas and speech related to such a marketplace of ideas. Some *amici curiae* might argue that adhering to the laws of nature doctrine will stifle innovation, but that is unlikely. With the laws of nature doctrine in place, this has been the most innovative era in the nation's history. Moreover, similar fears of discouragement of innovation voiced to the Court by the computer software industry during the *Benson* litigation were wisely directed to Congress, and have since proven to be misplaced. To the extent that the biotechnology sector now wants to exempt itself from longstanding legal precedent and to codify the Federal Circuit's holding in this case, that sector should also go first to Congress, to the extent such an approach is not constitutionally futile. Whether applied to new or old technology, the Court's non-patentability of laws of nature doctrine should be applied to all sectors with the same "general strictness." *Cf. Graham*, 383 U.S. at 19 (1966); *Chakrabarty*, 447 U.S. at 309, 315-316.

CONCLUSION

Metabolite's success in transmuting the Patent Act into an exclusive governmentally-issued license to preclude physicians, health care publishers, bioscience researchers, and citizens alike from merely thinking about a principle of human physiology underscores the importance of the issue presented. Upholding claim 13 of the '658 patent would be in conflict with patent jurisprudence and First Amendment values and is likely to retard, not promote, "the progress of Science and the useful Arts." The Court should reaffirm its rule that one cannot patent "laws of nature, natural phenomena, and abstract ideas," *Diehr*, 450 U.S. at 185, even if the patent applicant attempts to lay claim to such a law of nature by fractionating a single claim to make it appear that it relies on two, three, or more steps, where the only alleged innovation in the various steps and process is a law of nature. We urge the Court to reverse the Federal Circuit decision in this case.

Respectfully submitted,

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